UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,551	03/29/2004	Claudio Bucolo	P03491	3392

23702 7590 04/01/2009

Bausch & Lomb Incorporated
One Bausch & Lomb Place
Rochester, NY 14604-2701

EXAMINER
PACKARD, BENJAMIN J

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
04/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/812,551	**Applicant(s)** BUCOLO ET AL.	
	Examiner Benjamin Packard	**Art Unit** 1612	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 March 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,6-11,15-17,20,22,25-28 and 47*.
   Claim(s) withdrawn from consideration: *15-17*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☒ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). 1pg3/11/09 1pg3/16/09
13. ☐ Other: _____.

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612

/Benjamin Packard/
Examiner, Art Unit 1612

Continuation of 11. does NOT place the application in condition for allowance because: Claim Rejections - 35 USC § 103
Claims 1, 6-11, 25-28, and 47 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Singh et al (US Pregrant Pub 2003/0232089, see IDS dated 06/24/2004) in view of Olejnlk et al (US 5,597,599) and Gohzu et al (US 5,013,445).
Claim 20 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Singh et al (US Pregrant Pub 2003/0232089) in view of Olejnlk et al (US 5,597,599) and Gohzu et al (US 5,013,445), further in view of Cantoro et al (US 5,770,628).

Applicants suggest rather than discussing the rejections separately, the claims should be discussed as follows:
Group A: claims 1, 6, 8-10, 20, and 25-28
Applicants argue it would not be obvious to pick and choose among the various gums and optional ophthalmically acceptable mucoadhsive polymers, buffers, and nonionic osmolality agents, given the large number of potential combinations disclosed.
Examiner notes that the prior art together discloses the various components specifically based on function. Where the substitution of components based on their known function would be obvious to one of ordinary skill in the art, the focus then appears to be on the motivation for this specific combination. Applicant appears to focus on the total number of possible end compositions, but Examiner focuses on the various components which are disclosed as substitutable. Where the various groups of compounds are disclosed as substitutable and appear to be well known equivalents for the same purpose, the substitution of the various components would be well within the level of ordinary level of skill in the art to make such substitutions. Thus, even where a large number of potential combinations is possible, such combinations appear to result in nothing more than expected, a viscoelastic composition, given the addition of the gums it to produce a viscoelastic compositions ("transforming a drop of solution into a semisolids or gelatinous state after administration", paragraph 25 of Singh et al)
Group B: Claim 7
Applicants assert Singh is said to prefer non-ionic agents, and thus, one of ordinary skill would not be directed to ionic agents, given the widely accepted use of sodium chloride/phosphate buffer.
In response, Examiner points out while the rejection is made in light of what one of ordinary skill in the art would find obvious, the teaching which may be relied upon is not limited to what is most used in the art, but what is taught generally in the art. Again, where the prior art teaches variants of buffer systems, the ability to substitute the same based on their functional use would be obvious, i.e. buffer the system to a proper pH.
Group C: Claim 11
Applicants assert the composition provides a unique-long term stability as claimed in instant claim 11.
Examiner notes the cited specification section (page 17 bottom) states that while the specific combination had a higher free radical quenching than other samples without either, there is no evidence that other combinations had similar quenching. As such, an assertion of unexpected results does not appear to be supported by the specification.
Group D: Claim 15-17- currently withdrawn and not discussed
Group E: Claim 22
The composition of claim 22 requires a low molecular weight hydroxypropylmethylcellulose, which Applicants assert is not suggested in the prior art.
Examiner disagrees. Where hydroxypropylmethylcellulose compounds are taught in the prior art generally, as previously stated, absent evidence to the contrary, it would be obvious to pick known hydroxypropylmethylcellulose compounds used in ophthalmic solutions, such as disclosed in Katz et al.
Group F: Claim 42
Applicants assert claim 42 (Examiner assumes this is a typo for claim 47) is not obvious for the reasons stated above with regards to Group A.
Response to this group is made above in the Group A section.